SUMMARY OF SAFETY AND EFFECTIVENESS DATA

Dr Jan G Stannard
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Hanover, MA 02339-1629

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DEVICE
Trade Name Clear Bravo
Classification Name Pit and Fissure Sealant and Conditioner
FDA Product Code EBC 872 3765

JAN 22 2009

PREDICATE DEVICES
CosmeSeal Pit and Fissure Sealant
UltraSeal XT Pit and Fissure Sealant and Flowable Composite Kit
Delton Clear Pit and Fissure Sealant Kit

INDICATIONS FOR USE
Clear Bravo is a clear, light-cured pit and fissure sealant and sealer for application to the surfaces of teeth, sealing of composite margins and temporary restorations Clear Bravo is available in either fluoride and non-fluoride releasing formulas

DESCRIPTION AND INTENDED USE
Clear Bravo is a clear, light-cured pit and fissure sealant and sealer for application to the surfaces of teeth, sealing of composite margins and temporary restorations Clear Bravo is crystal clear which allows observation of conditions which may occur beneath the sealant This would include possible leakage, staining and also allows the use of caries detecting devices Clear Bravo is available in either fluoride and non-fluoride releasing formulas

COMPARISON WITH PREDICATE PRODUCTS

Clear Bravo has been found to be substantially equivalent in design, composition and intended use to the products listed above

SAFETY AND EFFECTIVENESS

The predicate products have been found substantially equivalent under the 510(k) premarket notification process as Class II Dental Devices under CFR 21

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 22 2009

Ms Jan G Stannard
President
Denali R&D Corporation
134 Old Washington Street
Hanover Massachusetts 02339-1629

Re K083473
Trade/Device Name Clear Bravo
Regulation Number 21 CFR 872 3765
Regulation Name Pit and Fissure Sealant and Conditioner
Regulatory Class II
Product Code EBC
Dated November 19, 2008
Received November 24, 2008

Dear Ms Stannard

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA) You may, therefore, market the device, subject to the general controls provisions of the Act The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898 In addition, FDA may publish further announcements concerning your device in the Federal Register

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807), labeling (21 CFR Part 801), good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820), and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act), 21 CFR 1000-1050

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807 97) For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474 For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464 You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address
http //www fda gov/cdrh/industry/support/index html

Sincerely yours,

Anthony D. Watson for
Ginette Y Michaud, M D
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510 (k) Number _____
(if known)

Device Name
Clear Bravo

Indications for Use

Clear Bravo is a clear, light-cured pit and fissure sealant and sealer for application to the surfaces of teeth, sealing of composite margins and temporary restorations Clear Bravo is available in either fluoride and non-fluoride releasing formulas

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Concurrence of CDRH, Office of Device Evaluation (ODE)

[illegible] Division Sign-Off)
[illegible]vision of Anesthesiology, General Hospital
[illegible]nfection Control, Dental Devices

510(k) Number K083473

Prescription Use __x____ *or* *Over-The-Counter Use*
(Per 21 CFR 801 109)